

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE: PHARMACEUTICAL INDUSTRY	)	MDL NO. 1456
AVERAGE WHOLESALE PRICE	)	
LITIGATION	)	CIVIL ACTION: 01-CV-12257-PBS
	)	Subcategory Docket: 06-CV-11337-PBS
	)	
THIS DOCUMENT RELATES TO	)	Judge Patti B. Saris
	)	
<i>U.S. ex rel. Ven-A-Care of the Florida Keys,</i>	)	Magistrate Judge Marianne B. Bowler
<i>Inc. v. Abbott Laboratories, Inc., et al., No.</i>	)	
06-CV-11337-PBS	)	
	)	

**UNITED STATES' SUR-REPLY TO ABBOTT'S REPLY STATEMENT OF  
UNDISPUTED MATERIAL FACTS SUPPORTING ITS MOTION FOR PARTIAL  
SUMMARY JUDGMENT AND ITS MOTION *IN LIMINE* TO EXCLUDE  
CERTAIN OPINIONS OF PLAINTIFFS' EXPERT MARK G. DUGGAN, PH.D.**

## **PRELIMINARY STATEMENT**

The United States submits this Sur-Reply to Abbott's Reply Statement of Undisputed Material Facts (Dkt. 6415/393) to assist the Court in determining which of the purported Undisputed Material Facts in Support of Abbott's Motion for Partial Summary Judgment ("Abbott's Statement of Undisputed Material Facts") (Dkt. 6189/243) are, and continue to be, disputed.<sup>1</sup> Unfortunately, this Sur-Reply is necessary because Abbott's Reply purports to set forth, among other things, Abbott's original, purportedly undisputed material statements of fact responded to by the government (*see* United States' Response to Abbott's Statement of Undisputed Material Facts) (Dkt. 6320/316) ("United States' Response"), and to which Abbott claims there is no genuine dispute. The United States responds that, contrary to assertions in Abbott's Reply, several of Abbott's facts are and continue to be disputed by the United States, as reflected in the United States' Response, or that the additional information provided by the United States in its Response is pertinent to the Court's consideration of the facts set forth by Abbott.

## **GENERAL REPLIES**

A. In the Preliminary Statement to its Reply, Abbott states that the United States' frequent response that "Abbott has correctly, but selectively, quoted excerpts" of documents and depositions lacks any legal basis, as Abbott is not required to include the entirety of a document or deposition. Abbott correctly notes that the Local Rules call for a "concise statement of the material facts" with "page references to affidavits, documents, and other documentation." D. Mass. Local R. 56.1. However, in cases where parties cite to the same document or testimony,

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<sup>1</sup> The United States continues to reserve its right to supplement and modify its responses to Abbott's Statement of Facts insofar as they profess to support Abbott's Motion *In Limine* To Exclude Certain Opinions Proffered by Plaintiffs' Expert Mark G. Duggan, Ph.D. (Dkt. 6175/233).

although selectively chose the language, the court should include both citations and consider the documents in their entirety. *Myers v. Life Ins. Co. of North America*, 2009 WL 742718 (N.D. Ill., March 19, 2009), citing *Foley v. City of Lafayette*, 359 F.3d 925, 928 (7th Cir. 2004). Moreover, where the parties disagree over relevant facts, the court sets forth the competing versions. *Id.* Accordingly, where Abbott has selectively cited to evidence, the United States has correctly set forth other relevant evidence that this Court should consider in determining whether a statement of fact is disputed. Although, in its Reply, Abbott often claims that the additional evidence is unresponsive, irrelevant or immaterial, where the United States disagrees, it respectfully refers the Court to the United States' Response.

B. Abbott also asserts in its Preliminary Statement that the United States' frequent response that witnesses' testimony was "given in their individual capacities," and not on "behalf of their respective States" or CMS, is immaterial and does not create a genuine dispute of the facts asserted therein. To the extent that Abbott has cited testimony of state or CMS officials as purported fact regarding the meaning of a law or regulation or the agency's official position, however, that is simply not the case. Under *United States v. Lachman*, 387 F.3d 42, 54-55 (1st Cir. 2004), the non-public or informal understandings of agency officials concerning the meaning of agency regulations are not relevant to interpreting the regulations. Even sworn testimony of former and present agency officials as to the agency's non-public understanding of a regulation are not entitled to deference. Only formal and public agency statements are relevant to interpreting a regulation. *Id.*

C. In its Reply to several of its Statements of Fact, Abbott impermissibly attempts to shift the burden to the United States to provide a factual basis for Abbott's purported undisputed material facts. Each of these attempts by Abbott should be rejected. To the extent that Abbott

has not provided a basis to support its assertions, those facts should not, as Abbott suggests, be “deemed admitted”.

### **SPECIFIC REPLIES**

**21.** As indicated in the United States’ Response, the United States admits to certain information contained in Abbott Statement of Fact No. 21, but Abbott Statement of Fact No. 21 is not admitted in its entirety. The broad assertions made by Abbott in the opening paragraph of Abbott Statement of Fact No. 21, and in Abbott’s Reply in support of Statement of Fact No. 21, are not supported by the record. Namely, Abbott’s attempt to make the sweeping assertion that state officials in this case had copies of the *Medicaid Pharmacy Bulletin*, read them, and believed them to contain useful and reliable information is overreaching. For example, in support of the assertion that state officials in this case believed that *Medicaid Pharmacy Bulletins* contained useful and reliable information, Abbott cites to the testimony of only two witnesses. One of the witnesses cited also testified that she did not agree with all of the information contained in the bulletins. Such testimony is relevant to the Court’s consideration of Abbott Statement of Fact No. 21. Accordingly, the United States respectfully refers the Court to the United States’ Response.

**22-26, 79, 85, 86, 89, 130, 135, 170, 171.**

The United States does not dispute these Abbott Statements of Fact but respectfully refers the Court to the United States’ Response to those Paragraphs, which include additional facts that are relevant, material and necessary to a more complete understanding of the issues raised by Abbott.

**27.** The United States does not dispute that Abbott correctly, but selectively cited to the testimony of certain Medicaid officials in its Statement of Fact No. 27. The United

States, however, respectively refers the Court to the United States' Response, which includes additional facts that are relevant, material and necessary to a more complete understanding of the issues raised by Abbott. For example, by selectively citing to portions of testimony of only a few Medicaid officials, Abbott attempts to generalize that state Medicaid programs permitted or were aware that their drug reimbursement systems paid a margin on ingredient cost to make up for inadequate dispensing fees. Importantly, however, as noted in the United States' Response, the weight of the testimony provided by state Medicaid officials shows that those officials believed their states' dispensing fees were adequate, their states did not have a policy or practice of allowing overpayments on ingredient costs to make up for purportedly inadequate dispensing fees, and that manufacturers never suggested to them that they were reporting inflated AWP's to make up for purportedly inadequate dispensing fees. The United States further disputes the assertion that it mischaracterized the September 4, 1994 State Medicaid Agency Regional Bulletin. As set forth in the United States' Response, states were required to make dispensing fee determinations separate and distinct from ingredient cost determinations.

**35.** The United States continues to dispute the characterization of the information in Abbott's Statement of Fact No. 35.

**37, 46.** The United States continues to dispute any attempt by Abbott to state conclusions or suggest inferences based on the cited documents that are not otherwise expressed on the face of the documents.

**41.** The United States continues to dispute the materiality of proposed, as distinct from enacted, legislation.

**44.** The United States does not dispute that the purpose of the December 1998 Program Memorandum from CMS to its fiscal intermediaries was to implement certain

provisions of the Balanced Budget Act of 1997, nor that the May 31, 2000 letter cited by Abbott was sent by Secretary Shalala to Congressman Bliley. The United States disputes, however, any suggestion that the Program Memorandum or Secretary Shalala's letter reflect a policy to pay inflated amounts for drugs, or that HHS sanctioned the reporting of false or fraudulent pricing to the compendia.

**48.** The United States continues to dispute Abbott's mischaracterization of the legislation and the purpose of the moratorium. The United States respectfully refers the Court to the United States' Response, which includes additional facts that are relevant, material and necessary to an understanding of the issues raised by Abbott.

**49.** The United States' Response stands. Importantly, despite Abbott's assertion to the contrary, *United States v. Lachman*, 387 F.3d 42 (1st Cir. 2004), is controlling. (See U.S. General Reply B., at p. 2, above). Further, as set forth in U.S. General Reply C., above, the burden is on Abbott, who attempts to assert legislative intent as an undisputed material fact in support of its motion for partial summary judgment, not the United States, to set forth the formal legislative record regarding the Congressional intent relating to Congress' passage of the Medicare Modernization Act.

**50-52, 59.** The United States' Response to Paragraphs 50-52 and 59 stands. Although the United States does not dispute that Abbott correctly, but selectively, cited portions of testimony, including testimony given by Dr. Vladeck, Ms. DeParle and Mr. Scully, to the extent Abbott contends that these witnesses' testimony provides their personal views, under *United States v. Lachman*, 387 F.3d 42 (1st Cir. 2004), those views are not relevant. (See U.S. General Reply B., at p. 2, above). Even if Abbott were to contend that the testimony is official testimony of CMS/HCFA, the testimony is incomplete and quoted out of context. For example,

Ms. DeParle testified that although average wholesale price had historically been determined by reference to the compendia, Medicare did not rely on the compendia for average wholesale prices. (5/18/07 DeParle Dep. at 229:4-21, St. Peter-Griffith Decl. Ex. 13). Ms. DeParle also testified that she understood the prices published by Red Book and Blue Book to be an actual average of wholesale prices paid in the marketplace, not prices which were set or controlled by drug manufacturers. (12/5/07 DeParle Dep. at 684:17-685:15, and 659:15- 660:5, St. Peter-Griffith Decl. Ex. 13). The United States further disputes Abbott's assertion that DOJ's "litigating position" differs from CMS's interpretation of AWP. Finally, the United States continues to dispute the materiality of Abbott Statement of Fact Nos. 50-52 and 59, based upon the rulings by the District Court construing the term "AWP" pursuant to its plain language and as a matter of law. *See In re Average Wholesale Price Litig.*, 460 F. Supp. 2d 277, 278 (D. Mass. 2006).

**53, 55.** The United States' Response to Paragraphs 53 and 55 stands, including the United States' dispute as to the relevance of the cited articles to Abbott's liability under the FCA. The United States disagrees that any portion of its Response to these Paragraphs are unresponsive or immaterial, especially to the extent that Abbott purports to be citing the articles referenced therein in support of a government approval defense.

**60.** The United States' Response stands. Although the United States does not dispute that the witnesses gave the testimony cited, Abbott cited such testimony selectively and out of context. Abbott's statement that the remainder of the United States' Response is irrelevant and immaterial for purposes of Abbott's motion is contested. The United States respectfully refers the Court to the United States' Response, which includes additional facts that are relevant, material and necessary to a more complete understanding of the issues raised by Abbott,

including that state Medicaid officials testified that they understood AWP to be defined according to its plain meaning; that they understood AWP to be an average of wholesale prices for a particular product; that they believed there to be a predictable relationship between AWP and actual market prices; and that they assumed manufacturers reported true and accurate prices to the compendia.

**61.** As stated in the United States' Response, the United States disputes the materiality but not the accuracy of the quoted testimony. The cited quotations, however, are selective, incomplete and misleading, and therefore the United States disputes the implied import of Paragraph 61, particularly to the extent that Abbott suggests that "the evidence overwhelmingly shows that state Medicaid officials understood that AWP prices reported in the compendia were not a reliable indicator of acquisition cost for generic drugs", as Abbott's Reply suggests. Abbott's statement is not supported by the record. This sweeping assertion by Abbott, alone, shows that the other testimony of state officials quoted in the United States' Response to Paragraph 61 is relevant and material. The United States respectfully refers the Court to the United States' Response, which includes additional facts necessary to an understanding of the issues raised by Abbott, including that state Medicaid officials testified that they understood AWP to be defined according to its plain meaning; that they understood AWP to be an average of wholesale prices for a particular product; that they believed there to be a predictable relationship between AWP and actual market prices; and that they assumed manufacturers reported true and accurate prices to the compendia.

**64-68, 70, 72-78.**

The United States continues to dispute the materiality of Paragraphs 64-68, 70 and 72-78. However, to the extent the Court determines that any of these Paragraphs are



material, the United States respectfully refers the Court to the United States' Response, which includes additional information necessary to an understanding of the issues raised by Abbott, including information pertaining to Abbott delaying and undermining the government's efforts to conduct its investigation. The United States further disputes that it "abused the seal period"; the United States' *ex parte* applications to extend the seal were appropriate and lawful.

**84.** The United States' Response to Abbott Statement of Fact No. 84 should not be deemed admitted. The United States respectfully refers the Court to the United States' Response, which includes additional information that is relevant, material and necessary to a more complete understanding of the issues raised by Abbott.

**87, 93, 128.** The United States' Responses to Abbott Statement of Fact Nos. 87 and 93 are not misleading. Abbott Statement of Fact Nos. 87 and 93 made the unqualified and inaccurate assertions that, other than for the States of Illinois, Florida, California, New Jersey, New York, Kentucky, Missouri, Michigan, Louisiana, and Wisconsin, Dr. Duggan's calculations did not rely upon claims data produced by the states. Abbott's Replies now attempt to modify its original Statement of Facts and unfairly measure the Response of the United States against never before stated versions of those facts. In addition, Abbott's Replies to Paragraphs 87, 93 and 128 are based upon immaterial semantics and inappropriate argument already included in its memoranda of law. (Defendants' Common Memorandum of Law (Dkt. 6429/409), pp. 40-41). Also, in the defendants' Response to U.S. Common Statement of Fact 116 (Dkt. 6439/415, p. 56), the defendants concede that they "*do not dispute that the United States' ... expert, Dr. Duggan, relied on (1) Medicaid data collected directly from the states, (2) SDUD, and (3) SMRF/MAX data.*" Abbott's only objection is that the United States describes all of the various types of data as "claims data" while defendants only want to refer to some of the data as claims data because

that enables them to dramatically articulate the false position that Dr. Duggan calculated damages even when he had no “claims” data. Thus, Abbott, not the United States, is being misleading. The underlying facts are not affected by these semantics. All of the data used by Professor Duggan was rooted in actual claims processed and paid by Medicare and Medicaid. (United States’ Local Rule 56.1 Statement of Undisputed Material Facts Common to All Defendants (Dkt. 6316/312, ¶ 116, and Henderson Common Exhibit 41 (Dkt. 6310/308) (Duggan Decl., ¶¶ 12-16)).

**91.** Abbott Statement of Fact No. 91 should not be deemed admitted. As stated in the United States’ Response, each step of Dr. Duggan’s methodology has been documented.

**105, 107.** The United States continues to dispute Abbott Statement of Fact Nos. 105 and the first sentence of Abbott Statement of Fact No. 107; they should not be deemed admitted. The factual basis for the United States’ Response to these Paragraphs is found at pages 116-127 of the December 11, 2008 deposition of Frank Tetkoski, Abbott Exhibit EJ.

**114.** As set forth in U.S. General Reply C., above, it is Abbott that needs to provide a factual basis for Paragraph 114, not the United States, because it is Abbott that seeks to use Paragraph 114 in support of its partial motion for summary judgment. Abbott’s inability to support its overly broad declaration that “Dr. Duggan did not analyze whether the number of units per claim is consistent across the states” cannot be blamed on the United States. In particular, the cited testimony, as conceded by Abbott in its Reply, only supports the minor point that Dr. Duggan did not use the units amount in the SDUD data (although Abbott fails to mention that Dr. Duggan did use the payment amount and the number of prescriptions).

**115.** Abbott Statement of Fact No. 115 does not accurately or completely summarize the testimony cited by Abbott; it should not be deemed admitted.

**117.** The first two sentences of Abbott Statement of Fact No. 117 should not be deemed admitted. The United States respectfully refers the Court to the United States' Response, which includes additional information that is relevant, material and necessary to a more complete understanding of the issue raised by Abbott. Further, as set forth in U.S. General Reply C., above, it is Abbott that needs to provide a factual basis for Paragraph 117, not the United States, because it is Abbott that seeks to use Paragraph 117 in support of its partial motion for summary judgment.

**120.** The United States continues to dispute Abbott's characterization of Dr. Duggan's testimony contained in Abbott Statement of Fact No. 120.

**121.** As set forth in U.S. General Reply C., above, it is Abbott that needs to provide a factual basis for Paragraph 121, not the United States, because it is Abbott that seeks to use Paragraph 121 in support of its partial motion for summary judgment. Abbott's inability to support its overly broad declarations, which pertain to every claim of various states, cannot be blamed on the United States. In particular, the cited testimony, only supports the lesser point that Dr. Duggan did not recall whether he analyzed that point for one state, Illinois. Abbott also fails to quote Dr. Duggan in context as on the prior page of the transcript he stated that he had done that type of analysis, (Abbott Ex. DU at 761:2-16).

Q. And I guess my overall question is this. When you do your analysis, are you attempting -- or did you reverse engineer the payments so that you can tie each of the claims to a recognized basis of payment, such as a charged amount, an AWP minus formula or a MAC?

MR. LAVINE: Object to form.

THE WITNESS: Some cases, I did. I believe that, for example, that I explored whether claims were paid at the charged amount.

And that varied to some extent over time and across states with respect in terms of the frequency with which that occurred. In other cases -- so I -- so I certainly did that to some extent.

**122-124, 127.**

The United States has and continues to dispute portions of Abbott Statement of Fact Nos. 122-124 and 127. The citations provided by Abbott do not support the factual assertions. Accordingly, Paragraphs 122-124 and 127 should not be deemed admitted. The United States respectfully refers the Court to the United States' Response, which includes additional information that is relevant, material and necessary to a more complete understanding of the issues raised by Abbott.

**133.** The United States objects to Abbott's Reply because it inappropriately modifies Abbott's original Statement of Fact (thereby confirming that the original Statement of Fact was not accurate). Abbott's attempt to portray the SMRF/MAX data as being aggregate data is simply wrong. Moreover, in Abbott's attempt to correct this misstatement, they have finally conceded that SMRF/MAX is "claims" data, contrary to the position taken, for example, in their Replies to Paragraphs 87, 93 and 128.

**157-166.** The United States continues to dispute Abbott Statement of Fact Nos. 157-166, to the extent that they assert that Dr. Duggan did not consider material information about specific state Medicaid programs' reimbursement methodologies in his calculations.

**169.** The United States' Response to Abbott Statement of Fact No. 169 stands. The United States' respectfully refers the Court to the United States' Response and Abbott Exhibit DS, so that the selective quotes contained in Abbott Statement of Fact No. 169 can be read in context and with the level of detail necessary to understanding the issues raised by Abbott.

**173.** The United States’ Response to Abbott Statement of Fact No. 173 stands. The United States’ respectfully refers the Court to the United States’ Response, which includes additional facts that are relevant, material and necessary to an understanding of the issues raised by Abbott. With respect to Abbott’s assertion that “[f]or portions of this time period, four states defined EAC exclusively in terms of WAC — Alabama, Florida, Massachusetts, and Rhode Island”, the United States notes, as it did in its Response, that the purported record evidence cited by Abbott does not supports it factual contention. The documents are excerpted, in some places unidentified, and are not documents that appear to bind the States of Alabama, Florida, Massachusetts, and Rhode Island. Accordingly, this assertion in Abbott Statement of Fact No. 173 should not be “deemed admitted”, as Abbott suggests.

Respectfully submitted,

For the United States of America,

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Dated: Sept. 22, 2009

## **CERTIFICATE OF SERVICE**

I hereby certify that I have this day caused an electronic copy of the above “United States’ Sur-reply to Abbott’s Reply Statement of Undisputed Material Facts and Supporting Its Motion for Partial Summary Judgment and its Motion *In Limine* to Exclude Certain Opinions of Plaintiffs’ Expert Mark G. Duggan, Ph.D.” to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Justin Draycott  
Justin Draycott

Dated: Sept. 22, 2009